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TO: Examiner Lakshmi Sarada Channavajjala - United States Patent and Trademark Office

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Application No.: 10/804,381

Inventor(s): Scott Edward Osborne et al.

Filed: March 19, 2004

Docket No.: 7892C

Confirmation No.: 7273

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/804,381
Inventor(s) : Scott Edward Osborne et al.
Filed : March 19, 2004
Art Unit : 1615
Examiner : Lakshmi Sarada Channavajjala
Docket No. : 7892C
Confirmation No. : 7237
Customer No. : 27752
Title : COMPOSITIONS FOR EFFICIENT RELEASE OF
ACTIVE INGREDIENTS

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

This Brief is filed pursuant to the appeal from the decision communicated in the Office Action mailed on December 20, 2006.

A timely Notice of Appeal was filed on March 16, 2007.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1-9 and 11-19 are pending in the present application. Claims 1-9 and 11-19 are rejected.

Claims 1-9 and 11-19 are appealed.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

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STATUS OF AMENDMENTS

A Response to Final Office Action without amendment of the claims was filed on March 16, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

In one aspect the invention is a release composition (see page 5, line 13) comprising:

- (1) from about $10^{-4}\%$ to about 20%, by weight of the release composition, of at least one skin care active (see page 6, line 27; page 8, lines 28-30), said skin care active comprising chitosan (see page 8, line 6);
- (2) from about 0.1% to about 60 %, by weight of the release composition, of a release agent (see page 9, line 1; page 13, lines 13-15); and
- (3) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant (see page 13, line 18), said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms (see page 14, lines 6-7);

wherein the release composition is semi-solid or solid at 20°C and at least partially transferable to a target skin surface (see page 25, line 33 to page 26, line 5).

In another aspect the invention is an article (see page 21, line 23 to page 23, line 30), comprising:

- a. a dispensing means (see page 21, line 10); and
- b. a release composition (see page 5, line 13) applied to at least a portion of the dispensing means, the release composition comprising:
 - (1) from about $10^{-4}\%$ to about 20%, by weight of the release composition, of at least one skin care active (see page 6, line 27; page 8, lines 28-30), said skin care active comprising chitosan (see page 8, line 6);
 - (2) from about 0.1% to about 60 %, by weight of the release composition,

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- of a release agent (see page 9, line 1; page 13, lines 13-15); and
- (3) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant (see page 13, line 18), said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms (see page 14, lines 6-7);

wherein the release composition is semi-solid or solid at 20°C and at least partially transferable to a wearer's skin (see page 25, line 33 to page 26, line 5).

In another aspect the invention a method for effectively delivering one or more skin care actives to skin, comprising:

- (a) applying to the skin an article comprising a dispensing means and a release composition disposed on at least a portion of the dispensing means (see page 21, lines 10-22);
- (b) transferring at least a portion of the release composition to the skin (see page 21, line 13);
- (c) exposing the release composition to moisture ; and
- (d) releasing one or more skin care active ingredients from the release composition;

wherein the release composition is semi-solid or solid at 20°C (see page 25, line 33 to page 26, line 5) and comprises:

- (1) from about 10⁻⁴% to about 20%, by weight of the release composition, of at least one skin care active (see page 6, line 27; page 8, lines 28-30), said skin care active comprising chitosan (see page 8, line 6);
- (2) from about 0.1% to about 60 %, by weight of the release composition, of a release agent (see page 9, line 1; page 13, lines 13-15); and
- (3) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant (see page 13, line 18), said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms (see page 14, lines 6-7).

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GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1—and 11-19 have been rejected under 35 USC §103(a) as being unpatentable over Roe (U.S. 5,643,588) in view of Johansson et al. (US 6,562,802).

ARGUMENTS

Claims 1-9 and 11-19

1. There is no suggestion or motivation to combine the cited references to achieve the lotion of Roe having chitosan as a skin care active as claimed in Claims 1-9 and 11-19.

The difference between the claimed invention and the prior art is the presence of chitosan as a skin care active in a lotion also having as an ingredient a skin protector.

In the Final Office Action the Examiner stated on page 6, "In contrast to applicants' argument that chitosan is not recognized for its skin care activity, Johansson teaches chitosan polymer as a skin protector (col. 8, line 51 – col. 10, line 25)."

The Examiner's point is exactly right, and this is why the claimed combination is not suggested by one of skill in the art.

The claimed invention has nothing to do with chitosan being used as a skin protector.

The claimed invention recites and relies on a paraffin wax as a skin protector, i.e., as a barrier protectant.

The claimed invention recites a barrier protectant in the form of paraffin wax, and a skin care active in the form of chitosan.

Therefore, even assuming that Roe discloses paraffin wax as a barrier protectant (it does not), there must be some motivation in the cited references to combine the chitosan of Johansson with the barrier protectant of Roe.

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But according to the Final Office Action, "Johansson teaches chitosan polymer as a skin protector".

The Final Office Action may be correct, but if correct, the argument fails. There can be no possible motivation to combine a skin protector (i.e., the chitosan of Johansson) with a lotion that already has a skin protector (i.e., the paraffin wax of Roe). If Roe already has a skin protector, why would the skilled person be motivated to add another ingredient identified as a skin protector?

Applicants maintain that the person of ordinary skill in the art would not be motivated to modify Roe to have an additional skin protectant, including the skin protectant identified as chitosan in the Final Office Action.

2. Johansson does not disclose chitosan as a skin care active.

In the Final Office Action the Examiner stated on page 6, "Further, examiner notes that instant claims do not recite any specific skin care activity by chitosan nor does the instant specification provide any definition with respect to the term skin care ..."

Applicants respectfully disagree.

The instant specification very definitely does provide a definition with respect to the term "skin care [active]".

At page 7, first paragraph, Applicants list exactly what skin care actives suitable for use in the claimed invention include. Skin care actives are described for many functions.

A skin care active is disclosed optionally as being a "skin protectant" but cannot be such in the claimed invention because there is already a skin protectant claimed. Therefore, in the claimed invention, a skin care active must be something other than a skin protectant.

Therefore, a skin care active of the claimed invention is one of a skin conditioning agent, pH control agent, etc.

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Johansson does not disclose chitosan as a skin care active, as disclosed and claimed in the instant application.

Johansson discloses chitosan as "a scavenger of skin irritating agents" in a "topical barrier formulation" (column 7, line 63).

Applicants submit that Roe never suggest the benefit of incorporating a scavenger of skin irritating agents, and therefore, there can be no possible motivation for a person of ordinary skill to combine the "scavenger of skin irritating agents" of Johansson as a skin care active in the lotion of Roe. Roe already has a topical barrier formulation, and would have absolutely no need to add in another, much less in the form of something as unusual as chitosan.

3. The Final Office Action fails to provide any teaching or suggestion to modify Roe in view of Johansson the add chitosan as a skin care active.

In the Final Office Action the Examiner stated on page 7, "Thus, the motivation to include chitosan of Johansson in the skin barrier protection composition of Roe comes from the skin barrier protecting effect of chitosan."

Applicants respectfully submit that this does not make sense.

Why would a lotion already having a skin barrier composition need another skin barrier composition?

The Final Office Action states that the "unexpected result is to protect skin from contacting with the bowel waste material."

But Roe already achieves this result.

What motivation could there possibly be to solve a problem already solved?

Applicants maintain there is none.

Moreover, Applicants maintain the arguments of previous responses (incorporated herein by reference), specifically the argument that the MPEP §2143.01 provides: "The

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mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (References omitted).

Applicants respectfully submit (and have shown) that there is absolutely no suggestion of the desirability of the combination. The combination is purely the result of picking and choosing among disparate disclosures to find a combination of ingredients based on hindsight.

Accordingly, Applicants respectfully submit that the Office Action has impermissibly relied upon hindsight to pick and choose ingredients from two disparate and unconnected references, neither of which have a nexus with the other. Such picking and choosing may result in each of the claim limitations being identified, but a prima facie case of obviousness requires that there be some motivation to combine references.

Applicants respectfully request the withdrawal of the 35 USC §103 rejection of Claim 1 and its dependent claims 2-9 and 11-13. Applicants also respectfully request the withdrawal of the 35 USC §103 rejection of Claim 14-19.

Claims 14-16:

In addition to the reasons provided above with respect to the claimed release composition, Claim 14 recites an article comprising a dispensing means.

The Office Actions to date fail to indicate why one skilled in the art knowledgeable about the particular dispensing means disclosed in Roe would have any motivation to modify the lotion of Roe based on Johansson which appears to disclose no dispensing means at all.

No response has been made to this argument.

Accordingly, Applicants respectfully submit that the Office Actions to date have failed to make any case, much less establish a prima facie case of obviousness in accordance with MPEP 2143 for Claims 14-16, and request the rejection be withdrawn.

Claims 17-19:

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In addition to the reasons provided above with respect to the claimed release composition, Claim 17 recites a method comprising "applying" by a dispensing means and "exposing to moisture".

The Office Action fails to indicate why one skilled in the art knowledgeable about the particular dispensing means disclosed in Roe would have any motivation to modify the lotion of Roe based on Johansson which appears to disclose no dispensing means at all.

Further, the Office Action fails to disclose where in either reference is found the method step of "exposing to moisture" to release one or more skin care active ingredients from a release composition, as claimed in Claim 17.

No response has been made to this argument.

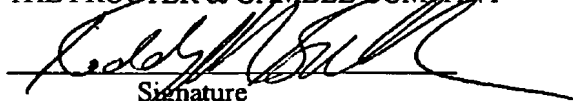
Accordingly, Applicants respectfully submit that the Office Actions to date have failed to make any case, much less establish a prima facie case of obviousness in accordance with MPEP 2143 for Claims 17-19, and request the rejection be withdrawn.

SUMMARY

In view of all of the above, it is respectfully submitted that Final Rejection be withdrawn and the pending Claims allowed.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY



Signature

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CLAIMS APPENDIX

1. A release composition comprising:
 - (4) from about $10^{-4}\%$ to about 20%, by weight of the release composition, of at least one skin care active, said skin care active comprising chitosan;
 - (5) from about 0.1% to about 60 %, by weight of the release composition, of a release agent; and
 - (6) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant, said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms;wherein the release composition is semi-solid or solid at 20°C and at least partially transferable to a target skin surface.
2. The release composition of Claim 1 wherein the skin care active has a water solubility of at least 0.1 grams of skin care active per 100 grams of water at 25°C.
3. The release composition of Claim 1 wherein the skin care active further comprises ingredients selected from the group consisting of skin protectants, protease inhibitors, chelating agents, pH control agents, anti-microbial agents, anti-biotics, vitamins and mixtures thereof.
4. The release composition of Claim 3 wherein the skin care active further comprises ingredients selected from the group consisting of hexamidine and its salts and derivatives, such as hexamidine diisethionate, triacetin, phytic acid, ethylenediamine tetraacetic acid, phenylsulfonyl fluorides, vitamins, and mixtures thereof.
5. The release composition of Claim 1 wherein the release agent is substantially hydrophilic and oleophilic.

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6. The release composition of Claim 1 wherein the release agent has a HLB value of at least about 3 and is selected from the group consisting of nonionic surfactants, polymeric surfactants, and mixtures thereof.
7. The release composition of Claim 6 wherein the nonionic surfactant is selected from the group consisting of alkoxyated C12-C50 fatty alcohols, alkoxyated C12-C50 fatty acids, alkoxyated C12-C50 fatty acid esters, alkoxyated C12-C50 fatty acid amides, wherein the nonionic surfactant is alkoxyated by C2-C6 alkoxyl groups and has a degree of alkoxylation from about 1 to about 110; glyceryl esters; sorbitan esters; alkyl glycosides; and their alkoxyated derivatives; and mixtures thereof.
8. The release composition of Claim 7 wherein the alkoxyl group is selected from the group consisting of ethoxy, propoxy, and mixtures thereof.
9. The release formulation of Claim 6 wherein the polymeric surfactant is selected from the group consisting of poloxomers, poloxamines, alkyl-substituted acrylic acid copolymers, and mixtures thereof.
10. (Cancelled)
11. The release composition of Claim 1 further comprising from about 0.1% to about 95% by weight of the release composition, of an emollient.
12. The release composition of Claim 11 wherein the emollient is selected from the group consisting of petroleum based emollients; polyolpolyester; fatty acid ester emollients; vegetable oils, hydrogenated vegetable oils and waxes; humectants; fatty alcohol ethers; and mixtures thereof.
13. The release composition of Claim 1 further comprising limited water soluble skin care

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actives selected from the group consisting of talc, topical starch, zinc oxide, zinc acetate, zinc carbonate, and the like, kaolin, live yeast cell derivatives, microporous cellulose, colloidal oatmeal, cholecalciferol, Peruvian balsam oil, protein hydrolysate, racemic methionine, Vitamin A, Vitamin E, and the like, aloe vera, and mixtures thereof.

14. An article, comprising:

- c. a dispensing means; and
- d. a release composition applied to at least a portion of the dispensing means, the release composition comprising:
 - (4) from about 10⁻⁴% to about 20%, by weight of the release composition, of at least one skin care active, said skin care active comprising chitosan;
 - (5) from about 0.1% to about 60 %, by weight of the release composition, of a release agent; and
 - (6) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant, said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms;

wherein the release composition is semi-solid or solid at 20°C and at least partially transferable to a wearer's skin.

15. The article of Claim 14 wherein the dispensing means is selected from the group consisting of a web substrate, an absorbent article, a tissue, a wipe, a sponge, a cotton ball, a pad, a non-woven, a patch, a bandage, paper, fabric, a canister, a stick, a stick casing, an aerosol dispenser, a roller, a pump spray, a trigger spray, and the like, and combinations thereof.

16. The article of Claim 14 wherein the dispensing means comprises an absorbent article.

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17. A method for effectively delivering one or more skin care actives to skin, comprising:

- (a) applying to the skin an article comprising a dispensing means and a release composition disposed on at least a portion of the dispensing means;
- (b) transferring at least a portion of the release composition to the skin;
- (c) exposing the release composition to moisture; and
- (d) releasing one or more skin care active ingredients from the release composition;

wherein the release composition is semi-solid or solid at 20°C and comprises:

- (1) from about 10⁻⁴% to about 20%, by weight of the release composition, of at least one skin care active, said skin care active comprising chitosan;
- (2) from about 0.1% to about 60 %, by weight of the release composition, of a release agent; and
- (3) from about 0.1% to about 95 %, by weight of the release composition, of a barrier protectant, said barrier protectant being a paraffin wax having about 16 to 50 carbon atoms.

18. The method of Claim 17 wherein the dispensing means is selected from the group consisting of a web substrate, an absorbent article, a tissue, a wipe, a sponge, a cotton ball, a pad, a non-woven, a patch, a bandage, paper, fabric, a canister, a stick, a stick casing, an aerosol dispenser, a roller, a pump spray, a trigger spray, and the like, and combinations thereof.

19. The method of Claim 17 wherein the skin care active further comprises ingredients selected from the group consisting of hexamidine and its salts and derivatives, such as hexamidine diisethionate, triacetin, phytic acid, ethylenediamine tetraacetic acid, phenylsulfonyl fluorides, vitamins, and mixtures thereof.

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20. (Cancelled)

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EVIDENCE APPENDIX

NONE

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RELATED PROCEEDINGS APPENDIX

NONE